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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,094	03/25/2004	Franco Castellini	BUGZ 200216	7674

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EXAMINER	
JOYNER, KEVIN	

ART UNIT	PAPER NUMBER
1744	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,094	CASTELLINI, FRANCO	
	Examiner	Art Unit	
	Kevin C. Joyner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/25/04, 9/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 13-15 recites the limitation "the third container" in line 2 of the claims. There is insufficient antecedent basis for this limitation in the claim. For examination purposes, the Examiner will read the claim as though it depends from claim 11.

4. Claim 16 recites the limitation "the third container" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. For examination purposes, the Examiner will read the claim as though it depends from claim 11.

5. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Line 1 of the claim discloses, "wherein it comprises product detection means." However, it is unclear as to what "it" is referring to in the claim. Thus, appropriate action is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-10, 12, and 18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Castellini (U.S. Publication No. 2002/0033362).

Concerning claims 1 and 2, Castellini discloses an apparatus for sterilizing and sanitizing water circuits, especially the water circuits of dental units comprising:

A user fluid supply line (1) connected, at one end to a mains water supply (2) and, at the other end to the dental unit through a first branch (3) for supplying a series of devices comprising a plurality of handpieces (5a-c); the apparatus being wherein it comprises:

at least one first unit (17 & 24) containing a first disinfecting/sterilizing fluid connected to a third independent branch (16) for supplying the first fluid at least to the first branch by being connected to the first branch to permit performance of programmable discontinuous sterilization or sanitization cycles in the first branch;

a second unit (15 & 23) containing a second sterile, disinfectant or medicinal fluid connected to the first branch and continuously supplying the second fluid to the first supply branch independently of, and as an alternative for, the user fluid from the supply line (paragraphs 18-20 and 25);

Control means (12) acting on at least one of the first and second units and designed to select the supply of the first or of the second fluid according to the operating configuration of the dental unit, that is to say, a continuous steady-state supply of the first branch or sterilization/disinfection cycles of the first branch (paragraphs 9 and 36-38).

Regarding claims 3 and 6, the reference also discloses that the second unit is equipped with a second control and selection means (22) that is capable of enabling a continuous supply of the second fluid, when required, in the first branch and is synchronized with means (9v) that is capable of supplying a user fluid and with first means (8v) for supplying a first disinfecting/sterilizing fluid (paragraphs 25, 27, and 38). More specifically, as disclosed in paragraph 25, the second control means supplies the second fluid in an alternative fashion to the first fluid. Therefore, the first fluid must be stopped by the means for supplying the user fluid, and the means for supplying the disinfectant must be started to introduce the disinfecting fluid. For this process to occur, the elements must be synchronized to provide a fully functional apparatus. Concerning claim 4, Castellini discloses that the second unit that supplies the second fluid is connected directly to the first fluid supply branch (paragraph 25) as shown by the branch labeled numeral 7 in Figure 1. With regard to claim 5, Castellini also discloses that the second unit that supplies the second fluid is connected to the third independent branch (16) leading into the first branch (3) as disclosed in paragraph 25 and shown in Figure 1.

Concerning clams 7 and 9, the reference continues to disclose that the first unit comprises at least one first container (17), holding the first or the second fluid, and first means (19) for extracting the first or second fluid and introducing it into the third branch (16) in paragraphs 27-30. Regarding claim 8, the first containers (17) at the first extraction means (24) are interchangeable and independent, and are fully capable of containing the first and second fluids (paragraph 22). With regard to claim 10, the second unit comprises a second container (15) that is capable of holding the second fluid consisting of a liquid mixed with a suitable product to produce a second sterile, disinfectant or medicinal fluid; the second container being removably connected, through a stable fastening element (18) equipped with second means (23) for extracting the second fluid mixture (paragraphs 18 and 27).

Regarding claim 12, the reference also discloses that the control means (12) comprises a logical selection unit connected to the first and second means that is capable of selecting the first or second fluid supply according to required operating elements, and designed to enable continuous supplying of the second fluid to each single handpiece selected or to perform cycles of predetermined length and with predetermined quantities of the first fluid in paragraphs 37-40. Concerning claims 18-23, that apparatus is fully capable of utilizing various mixtures of purified sterile water mixed with a disinfectant or medicinal product. Most notably, a liquid of 0.1% physiological saline solution and a disinfectant or medicinal product, hydrogen peroxide and water at a concentration of between 0.1-3%, Chlorhexidine and sterile water at a

final concentration of between 0.002 and 0.2, and Triclosan and a liquid at a final concentration of between 0.005 and 0.5.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 11, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castellini (U.S. Publication No. 2002/0033362) in view of Belfer et al. (U.S. Patent No. 6,142,170).

Castellini is relied upon as set forth above. Furthermore regarding claim 11, Castellini discloses that the second container is capable of holding; a sterile liquid, a disinfectant, or a medicinal product acting in such a way as to supply at least the first branch with a second fluid having properties suitable for the treatment to be carried out. However, Castellini does not appear to disclose another container holding a fluid to be mixed with the fluid from the second container by respective dosing means acting between the two containers. Belfer discloses an apparatus for sterilizing and sanitizing water circuits of dental units comprising a user supply line and a first branch (146). The reference continues to disclose that the apparatus further comprises two containers (16 as shown in Figure 1) capable of holding a sterile liquid in one container and a disinfectant or medicinal product in the other container to be mixed with the sterile liquid

by a respective dosing means acting between the two containers in such a way as to supply at least the first branch with a fluid having properties suitable for the treatment to be carried out (columns 6 & 7, lines 60-68 & 1-5; column 5, lines 50-60) in order to provide two disinfecting solutions to clean, disinfect, filter, and scrub the water lines in a dental system. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Castellini to include in the second unit two containers capable of holding a sterile fluid in one container and a disinfectant or medicinal product in the other to be mixed with the sterile liquid by a respective dosing means acting between the two containers in order to provide one uniform solution to perform two different tasks on a water line such as cleaning, disinfecting, filtering, and/or scrubbing as exemplified by Belfer. Concerning claims 13-15, the containers of Castellini are fully capable of holding the product in a liquid, powder, or granulated form.

Concerning claim 16, Castellini in view of Belfer is relied upon as set forth in reference to claim 11. All of the containers of Castellini are connected to a respective cap (18) equipped with a cannula (20) for extracting the product as such is a commonly known system for extracting solutions. Belfer continues to disclose that the two containers of various types (column 8, lines 11-20) are connected through a respective conduit, to a branch for supplying the second container equipped with the dosing means as shown in Figures 2a-c. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a third container connected through a respective conduit, to a branch for supplying a second container equipped with a dosing

means in order to provide one uniform solution to perform two different tasks on a water line such as cleaning, disinfecting, filtering, and/or scrubbing as exemplified by Belfer. It is noted that one of ordinary skill in the art that modifying the apparatus in Castellini with additional containers as shown by Belfer would provide the additional containers with caps and cannulas as required by Castellini.

Claims 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castellini (U.S. Publication No. 2002/0033362) in view of Behringer (WO 02/15811- English Equivalent U.S. Patent No. 7,056,472).

Castellini is relied upon as set forth above. Castellini continues to disclose that the second control (22) is coordinated with the means (9v) that supply the fluid from the mains so as to allow the second container unit to introduce the second sterile disinfectant or medicinal fluid into the mains supply line. Castellini does not appear to disclose that the second fluid is simultaneously introduced into the mains fluid from the supply line. Behringer discloses an apparatus for sterilizing water circuits of dental units comprising a user fluid supply line connected to a mains water supply (3) and a dental unit (1) through a first branch (2). The apparatus continues to disclose that a second container unit (5) simultaneously introduces a second sterile disinfectant fluid into the mains fluid from the supply line in order to provide a system that sterilizes the water circuit while it is being used (column 4, lines 33-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Castellini to allow the second container unit to simultaneously introduce the second sterile fluid into the mains fluid from the supply line in order limit any

unnecessary down time that may be caused for sterilization purposes as exemplified by Behringer.

Regarding claim 24, as explained above, Castellini discloses that the first unit and the control means act upon one another to provide a series of operable functions. Castellini does not appear to disclose that the apparatus comprises a product detection means capable of acting on the first unit and on the control means to enable activation of a continuous supply cycle when the second fluid is detected and a discontinuous sterilization cycle when the first fluid is detected. However, Behringer continues to disclose a product detection means capable of acting to enable activation of a continuous supply cycle when a second fluid is detected and a discontinuous sterilization cycle when a first fluid is detected in order to provide the most effective disinfecting fluid to the water circuit at any given time in column 3, lines 30-65. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Castellini to include a product detection means capable of acting to enable activation of a continuous supply cycle when a second fluid is detected and a discontinuous sterilization cycle when a first fluid is detected in order to provide the most effective disinfecting fluid to the water circuit at any given time as exemplified by Behringer.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-10 and 18-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-20 of U.S. Patent No. 6,612,838 in view of Castellini (U.S. Publication No. 2002/0033362). Claims 13-20 of '838 disclose all the limitations of claims 1-10 and 18-23 of the instant application except for an extraction means to extract the fluids from the two units, or a second control means for supplying a second fluid. However, as discussed above Castellini (U.S. Publication No. 2002/0033362) discloses both of these limitations comprising an extraction means in order to extract the fluids from the two units, or a second control means in order to supply a second fluid. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of '838 to include an extraction means in order to extract the fluids from the two units, and a second control means in order to supply a second fluid as disclosed by Castellini.

7. Claims 11 and 13-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-20 of U.S. Patent No.

6,612,838 in view of Castellini (U.S. Publication No. 2002/0033362) as applied to claims 1-10 and 18-23 above, and further in view of Belfer et al. (U.S. Patent No. 6,142,170).

As discussed above, claims 13-20 of '838 in view of Castellini disclose all the limitations of claims 11 and 13-16 except for a second unit comprising a third container holding a medicinal product and a dosing means utilized to mix the products from the second and third container in the second unit. However, as discussed above Belfer discloses a second unit comprising a third container holding a medicinal product and a dosing means utilized to mix the products from the second and third container in the second unit in order to provide one uniform solution to perform two different tasks on a water line. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of '838 in view of Castellini to include a second unit comprising a third container holding a medicinal product and a dosing means utilized to mix the products from the second and third container in the second unit in order to provide one uniform solution to perform two different tasks on a water line as exemplified by Belfer.

8. Claims 17 and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-20 of U.S. Patent No. 6,612,838 in view of Castellini (U.S. Publication No. 2002/0033362) as applied to claims 1-10 and 18-23 above, and further in view of Behringer (WO 02/15811- English Equivalent U.S. Patent No. 7,056,472).

As discussed above, claims 13-20 of '838 in view of Castellini contains all the limitations of claim 17 except for the limitation that the second fluid is simultaneously

introduced into the mains fluid from the supply line. Behringer discloses this conventional teaching however wherein the apparatus discloses a second container unit simultaneously introducing a second sterile disinfectant fluid into the mains fluid from the supply line in order to provide a system that sterilizes the water circuit while it is being used. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of '838 in view of Castellini to include a second container unit simultaneously introducing a second sterile disinfectant fluid into the mains fluid from the supply line in order to provide a system that sterilizes the water circuit while it is being used as exemplified by Behringer

Regarding claim 24, '838 in view of Castellini discloses all the limitations of claim 24 except for a product detection means capable of acting on the first unit and on the control means to enable activation of a continuous supply cycle when the second fluid is detected and a discontinuous sterilization cycle when the first fluid is detected. However, Behringer also discloses a product detection means capable of acting to enable activation of a continuous supply cycle when a second fluid is detected and a discontinuous sterilization cycle when a first fluid is detected in order to provide the most effective disinfecting fluid to the water circuit at any given time. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of '838 in view of Castellini to include a product detection means capable of acting to enable activation of a continuous supply cycle when a second fluid is detected and a discontinuous sterilization cycle when a first fluid is detected in order to

provide the most effective disinfecting fluid to the water circuit at any given time as exemplified by Behringer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Joyner whose telephone number is (571) 272-2709. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCJ

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SUPERVISORY PATENT EXAMINER